

From: [James Murray](#)
To: [Kershen, Drew L.](#); [Mark Walton](#); [Strauss, Steven](#); "Henry Miller"
Cc: [Robert Friedman](#); gary.marchant@asu.edu; [Dennis Karjala](#); [Joshua Abbott](#); ystevens@asu.edu; [alan mchughen](#); prakash@mytu.tuskegee.edu; tpr@geeclaw.com; bchassy@illinois.edu; jsax@cwsu.edu; [Charles Arntzen](#); [Alison Van Eenennaam](#); nvf1@psu.edu; amassey@bio.org; [Wozniak, Chris](#); [Sarah Carter](#); lvg@outlook.com; jon@jonentine.com; kfolta@ufl.edu; [Kent J Bradford](#); [Shane Morris](#); [James Collins](#); bslutsky@amseed.org; [Guy Cardineau](#); [Josette Lewis](#); [Deborah Relph](#); [Lauren Burkhart](#)
Subject: RE: Jan 14 Genetic Modification Workshop at ASU
Date: Friday, January 02, 2015 6:27:58 PM

Amen brother to point 3!

jim

From: Kershen, Drew L. [<mailto:dkershen@ou.edu>]
Sent: Friday, January 02, 2015 3:23 PM
To: Mark Walton; Strauss, Steven; 'Henry Miller'
Cc: Robert Friedman; Gary Marchant; Dennis Karjala; Joshua Abbott; ystevens@asu.edu; alan mchughen; prakash@mytu.tuskegee.edu; tpr@geeclaw.com; bchassy@illinois.edu; jsax@cwsu.edu; Charles Arntzen; Alison Van Eenennaam; nvf1@psu.edu; amassey@bio.org; wozniak chris; Sarah Carter; lvg@outlook.com; jon@jonentine.com; kfolta@ufl.edu; Kent J Bradford; Shane Morris; James Collins; James Murray; bslutsky@amseed.org; Guy Cardineau; Josette Lewis; Deborah Relph; Lauren Burkhart
Subject: RE: Jan 14 Genetic Modification Workshop at ASU

Dear Friends,

Today we have had a goodly number of comments about the Andrew Pollack NYT article about Scott's Fescue that USDA has decided is outside USDA regulatory review. A similar, though I think more balanced, article is the one from Capital Ag Press by Mateuz Perkowski.

I will make several points about regulation in the context of our discussion today.

Point One. I agree with the posts that Wayne Parrott made today. I agree with him that the question now should not be -- what to regulate?, but why are we regulating?

1. The "what to regulate" question has led to the illogical and unscientific (not to mention unpredictable and Kafkaesque) situation in which the US finds its regulatory system today. If we begin with the "why" I think it means we refocus regulation on the product and its actual risks (harms), as opposed to the process which presently triggers US regulatory efforts and regulatory efforts in the EU plus the Cartagena Protocol. A simple return to the product and its actual risks -- all of which is and would have been perfectly doable under the US laws invoked for regulation-- would do wonders for our regulatory system.
2. If the US regulatory agencies had focused on product and risk, the USDA-APHIS would not have created a "regulated article" category; the EPA would not have expanded its FIFRA authority to find a Plant-Incorporated-Protectant (i.e. plants as pesticides) hidden in FIFRA; FDA would not be regulating improved bred-salmon or horn-less cattle as "new veterinary drugs." Simple common sense focus on product and risk would not have created the illogical and unscientific categorizations

that now characterize US regulatory policies. Products with risk is completely within the regulatory laws of the US, if the agencies had acted with common sense in the past or acted with common sense in the present.

Point Two. Be careful with the “escaped regulation” theme of the Pollack and Perkowski articles. USDA has said that a number of plants bred by using new breeding techniques, including biolistics, are outside its authority. I think the USDA is correct. But even if the USDA removes itself from the regulatory picture, the EPA and FDA are stepping into the regulatory breach. EPA is searching mightily to find “definitions” either in FIFRA (Federal Insecticide, Fungicide, Rodenticide Act) or TSCA (Toxic Substances Control Act) that would allow EPA to replace the absent USDA-APHIS regulatory structure. Going from the USDA-APHIS to EPA oversight does not count, in my book, as escaping regulation. In addition, please remember that FDA has declared, formally in 2008/2009, that any animal modified by molecular breeding techniques is per se determined to be a “new animal drug” subject to the FDCA (Federal Food, Drug, Cosmetic Act) regulations. Going from USDA-APHIS to FDA, I repeat myself, does not count as escaping regulation.

Point Three. Even if new breeding techniques do not result in mandatory regulatory approvals before release in the U.S., I am sadly confident in predicting that these new breeding techniques will classify as GMOs under EU, New Zealand, and (probably) Cartagena Protocol statutes, regulations and international agreements. Thus, these “unregulated” products released into U.S. markets will be subject to regulation in other nations. Being subject to other nations’ regulatory schemes creates the “rejected” consequences we have seen for Syngenta, DuPont/Dow, and Bayer products in international trade. This international rejection means two things (at least), in my opinion: 1) a form of a “veto” by other nations over agricultural biotechnology in the U.S. until regulatory approval is obtained in these import nations; 2) U.S. law suits against companies in the U.S. that have released traits lacking approval in major import markets. These veto and lawsuit consequences are likely to have very detrimental impacts on agricultural biotechnology and innovation in the U.S. and elsewhere.

Drew

Drew L. Kershen
Earl Sneed Centennial Professor of Law (Emeritus)
University of Oklahoma, College of Law
300 West Timberdell Road
Norman, Oklahoma 73019-5081 U.S.A.
p 1-405-325-4784
f 1-405-325-0389
dkershen@ou.edu
<http://jay.law.ou.edu/faculty/kershen/>
<http://works.bepress.com/drew.kershen/>
<http://ssrn.com/author=285854>

Drew L. Kershen
Earl Sneed Centennial Professor of Law (Emeritus)
University of Oklahoma, College of Law

300 West Timberdell Road
Norman, Oklahoma 73019-5081 U.S.A.
p 1-405-325-4784
f 1-405-325-0389
dkershen@ou.edu
<http://jay.law.ou.edu/faculty/kershen/>
<http://works.bepress.com/drew.kershen/>
<http://ssrn.com/author=285854>

From: Mark Walton [<mailto:mark@recombinetics.com>]
Sent: Friday, January 02, 2015 4:28 PM
To: Strauss, Steven; 'Henry Miller'
Cc: Robert Friedman; Gary Marchant; Dennis Karjala; Joshua Abbott; ystevens@asu.edu; Kershen, Drew L.; alan mchughen; prakash@mytu.tuskegee.edu; tpr@geeclaw.com; bchassy@illinois.edu; jsax@cwsu.edu; Charles Arntzen; alvaneenennaam@ucdavis.edu; nvf1@psu.edu; amassey@bio.org; wozniak chris; Sarah Carter; lvq@outlook.com; jon@jonentine.com; kfolta@ufl.edu; kjbradford@ucdavis.edu; Shane Morris; James Collins; jdmurray@ucdavis.edu; bslutsky@amseed.org; Guy Cardineau; jolewis@ucdavis.edu; Deborah Relph; Lauren Burkhart
Subject: RE: Jan 14 Genetic Modification Workshop at ASU

Andy's (and the NY *Times* in general) bias can be seen in the headline, "companies avoid regulation." It could have been titled differently, e.g. "Do GM Regulations Apply to Gene Editing" and served as a discussion starter. Instead it sets the stage for future battles.

I do believe it is relevant to our discussion. If we hope to make any significant change in regulation we will have to deal with the biases evidenced in the *Times* article in a way that allows the political process time and space to work.

Mark

Mark Walton, Ph.D.
Chief Marketing Officer
Recombinetics
Direct: +1 512.505.8101
Cell: +1 512.799.1636
Skype: +1 512.961.7056
Corporate Office: 1246 University Avenue W, Suite 301, St. Paul, MN 55104
www.recombinetics.com

"We've arranged a global civilization in which most crucial elements profoundly depend on science and technology. We have also arranged things so that almost no one understands science and technology. This is a prescription for disaster. We might get away with it for a while, but sooner or later this combustible mixture of ignorance and power is going to blow up in our faces." – Carl Sagan

From: Strauss, Steven [<mailto:Steve.Strauss@oregonstate.edu>]
Sent: Friday, January 02, 2015 4:11 PM
To: 'Henry Miller'; Mark Walton

Cc: Robert Friedman; Gary Marchant; Dennis Karjala; Joshua Abbott; ystevens@asu.edu; dkershen@ou.edu; alan mchughen; prakash@mytu.tuskegee.edu; tpr@geeclaw.com; bchassy@illinois.edu; jsax@cwsl.edu; Charles Arntzen; alvaneenennaam@ucdavis.edu; nvf1@psu.edu; amassey@bio.org; wozniak chris; Sarah Carter; lvg@outlook.com; jon@jonentine.com; kfolta@ufl.edu; kjbradford@ucdavis.edu; Shane Morris; James Collins; jdmurray@ucdavis.edu; bslutsky@amseed.org; Guy Cardineau; jolewis@ucdavis.edu; Deborah Relph; Lauren Burkhart

Subject: RE: Jan 14 Genetic Modification Workshop at ASU

I am not sure about the long standing issues with Pollack, but I thought the article was quite reasonable...but we can explore perhaps at the meeting at ASU if relevant to our discussions....

Steve Strauss, Professor, Oregon State University

Cell: 541 760 7357 -- <http://people.forestry.oregonstate.edu/steve-strauss/>

From: Henry Miller [<mailto:henry.miller@stanford.edu>]

Sent: Friday, January 02, 2015 1:54 PM

To: Mark Walton

Cc: Robert Friedman; Gary Marchant; Dennis Karjala; Joshua Abbott; ystevens@asu.edu; dkershen@ou.edu; alan mchughen; prakash@mytu.tuskegee.edu; Strauss, Steven; tpr@geeclaw.com; bchassy@illinois.edu; jsax@cwsl.edu; Charles Arntzen; alvaneenennaam@ucdavis.edu; nvf1@psu.edu; amassey@bio.org; wozniak chris; Sarah Carter; lvg@outlook.com; jon@jonentine.com; kfolta@ufl.edu; kjbradford@ucdavis.edu; Shane Morris; James Collins; jdmurray@ucdavis.edu; bslutsky@amseed.org; Guy Cardineau; jolewis@ucdavis.edu; Deborah Relph; Lauren Burkhart

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In case any of you are unaware of Pollack's long-standing biases and incompetence in writing about agbiotech, see: <http://www.forbes.com/2010/05/19/science-new-york-times-agriculture-opinions-columnists-henry-i-miller.html> and <http://www.forbes.com/2010/06/30/new-york-times-media-bias-opinions-columnists-henry-miller.html>.

From: "Mark Walton" <mark@recombinetics.com>

To: "Robert Friedman" <rfriedman@jcv.org>, "Gary Marchant"

<Gary.Marchant@asu.edu>, "Dennis Karjala" <DENNIS.KARJALA@asu.edu>, "Joshua

Abbott" <Josh.Abbott@asu.edu>, ystevens@asu.edu, dkershen@ou.edu, "alan

mchughen" <alan.mchughen@ucr.edu>, prakash@mytu.tuskegee.edu, "steve Strauss"

<steve.Strauss@oregonstate.edu>, tpr@geeclaw.com, bchassy@illinois.edu, "henry

millier" <henry.miller@stanford.edu>, jsax@cwsl.edu, "Charles Arntzen"

<Charles.Arntzen@asu.edu>, alvaneenennaam@ucdavis.edu, nvf1@psu.edu,

amassey@bio.org, "wozniak chris" <wozniak.chris@epa.gov>, "Sarah Carter"

<scarter@jcv.org>, lvg@outlook.com, jon@jonentine.com, kfolta@ufl.edu,

kjbradford@ucdavis.edu, "Shane Morris" <Shane.Morris@NRCan-RNCan.gc.ca>, "James

Collins" <jcollins@asu.edu>, jdmurray@ucdavis.edu, bslutsky@amseed.org, "Guy

Cardineau" <Guy.Cardineau@asu.edu>, jolewis@ucdavis.edu

Cc: "Deborah Relph" <Deborah.Relph@asu.edu>, "Lauren Burkhart"

<Lauren.Rashi@asu.edu>

Sent: Friday, January 2, 2015 1:17:31 PM

Subject: RE: Jan 14 Genetic Modification Workshop at ASU

Hello everyone,

Andy Pollack wrote a piece describing what he calls a “lack of oversight” of the new methods of genetic engineering. It was published today. The link to the article is here:

http://www.nytimes.com/2015/01/02/business/energy-environment/a-gray-area-in-regulation-of-genetically-modified-crops.html?ref=science&_r=0

Mark

Mark Walton, Ph.D.

Chief Marketing Officer

Recombinetics

Direct: +1 512.505.8101

Cell: +1 512.799.1636

Skype: +1 512.961.7056

Corporate Office: 1246 University Avenue W, Suite 301, St. Paul, MN 55104

www.recombinetics.com

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From: Friedman, Robert [<mailto:rfriedman@jcv.org>]

Sent: Wednesday, December 24, 2014 12:03 PM

To: Gary Marchant; Dennis Karjala; Joshua Abbott; ystevens@asu.edu; dkershen@ou.edu; alan.mchughen@ucr.edu; prakash@mytu.tuskegee.edu; steve.Strauss@oregonstate.edu; tpr@geeclaw.com; bchassy@illinois.edu; henry.miller@stanford.edu; jsax@cwsu.edu; Charles Arntzen; alvaneenennaam@ucdavis.edu; nvf1@psu.edu; amassey@bio.org; wozniak.chris@epa.gov; Carter, Sarah; lvg@outlook.com; jon@jonentine.com; kfolta@ufl.edu; kjbradford@ucdavis.edu; Shane.Morris@NRCan-RNCan.gc.ca; James Collins; jdmurray@ucdavis.edu; bslutsky@amseed.org; Guy Cardineau; jolewis@ucdavis.edu; Mark Walton

Cc: Deborah Relph; Lauren Burkhart

Subject: RE: Jan 14 Genetic Modification Workshop at ASU

Hi all—

For those who may not have seen this, PLoS biology has a new collection, “The Promise of Plant Translational Research”. The four overview essays were published in June and are good additions to the readings posted so far.

<http://www.ploscollections.org/article/browse/issue/info:doi/10.1371/issue.pcol.v01.i25> .

Bob

Robert M. Friedman
Vice President for Policy and University Relations
J. Craig Venter Institute
4120 Capricorn Lane, La Jolla, CA 92037
9704 Medical Center Drive, Rockville, MD 20850
phone: 858-200-1810
cell phone: 240.888.9801

From: Gary Marchant [<mailto:Gary.Marchant@asu.edu>]
Sent: Friday, October 24, 2014 2:14 PM
To: Gary Marchant; Dennis Karjala; Joshua Abbott; y Stevens@asu.edu; dkershen@ou.edu; alan.mchughen@ucr.edu; prakash@mytu.tuskegee.edu; steve.Strauss@oregonstate.edu; tpr@geeclaw.com; bchassy@illinois.edu; henry.miller@stanford.edu; jsax@cwsl.edu; Charles Arntzen; alvaneenennaam@ucdavis.edu; nvf1@psu.edu; amassey@bio.org; wozniak.chris@epa.gov; Carter, Sarah; Friedman, Robert; lvq@outlook.com; jon@jonentine.com; kfolta@ufl.edu; kjbradford@ucdavis.edu; Shane.Morris@NRCan-RNCan.gc.ca; James Collins; jdmurray@ucdavis.edu; bslutsky@amseed.org; Guy Cardineau; jolewis@ucdavis.edu; mark@recombinetics.com
Cc: Deborah Relph; Lauren Burkhart
Subject: Jan 14 Genetic Modification Workshop at ASU

Dear Workshop Participant – on behalf of the Planning Committee, thank you for agreeing to participate in our workshop on “Directed Genetic Modification Technologies: An Opportunity for Science-Based Regulatory Reform” on January 14 in Scottsdale Arizona. Here are some logistics for the workshop:

1. We have an excellent group of participants (see attached list). Please send me any corrections on how you would like your name and affiliation listed on the final program. The meeting room only holds 30 people in its large roundtable set-up, so we are at maximum capacity and unfortunately will not be able to accommodate any other participants.
2. The workshop will be held at the ASU Skysong facility, 1475 North Scottsdale Road in Scottsdale, Arizona. This facility is about a 10 minute cab ride from the Phoenix airport (Sky Harbor).
3. The workshop will run from 9 am to 4:30 pm. We will send out an agenda in the next couple weeks. Most of the time on the agenda will be devoted to roundtable discussion, with just a few short presentations to start the discussions.
4. After the workshop, at 5 pm, we will be hosting an optional dinner for those staying over and wishing to attend at Los Sombreros, which is located close to the workshop site and features a unique and delicious type of Mexican food, a great ambience, and excellent Margaritas. ***Please let my assistant Debb Relph (Deborah.relph@asu.edu and cc'd above) if you plan to attend the dinner so we can make a reservation for the appropriate number of people.***
5. For those of you traveling from out of town, please go ahead and make your own flight reservations and we will reimburse you. Per our university rules, we can only reimburse economy fare flights. We will also reimburse you for airport parking, taxis, and other reasonable travel expenses. We will be arranging ground transportation between the hotel and meeting site, so you should not need a rental car and can use taxis to get to and from the Phoenix airport.
6. We have reserved and paid for a block of rooms at the Tempe Aloft hotel, the closest

nice hotel to the meetings site (5 minutes away). ***Please let Debb Relph (Deborah.relph@asu.edu and cc'd above) know which nights you would like a room for and she will make a reservation for you.***

7. We have created a password-protected site for materials related to the workshop at <http://conferences.asucollegeoflaw.com/gmotech/>. The password is: asugmo. This site includes a folder of relevant articles and writings on the topic of new directed genetic modification technologies. We have not screened these articles for how credible or valid they are – but rather wanted to create a repository for your availability of all different perspectives and positions on these issues. The repository is certainly incomplete – please feel free to send me any other articles or papers you think relevant.
8. We are working to create an online forum for pre- and post-workshop discussion among participants. We will send out info about that forum soon.

Thanks again for your participation, and we will be sending additional info on agenda, online forum, etc soon. In the meantime, please feel free to send me any questions, concerns or suggestions. We look forward to a great workshop on January 14.

Gary Marchant on behalf of the Workshop Planning Committee

Gary Marchant, ASU
Dennis Karjala, ASU
Joshua Abbott, ASU
Yvonne Stevens, ASU
Drew Kershen, U. Oklahoma College of Law
Alan McHughen, UC Riverside
Channapatna Prakash, Tuskegee
Steven Strauss, Oregon State

Gary Marchant, Ph.D., J.D.
Regents' Professor and Lincoln Professor of Emerging Technologies, Law & Ethics
Faculty Director, Center for Law, Science & Innovation,
Sandra Day O'Connor College of Law
Professor, School of Life Sciences
Distinguished Sustainability Scientist, Global Institute of Sustainability
Arizona State University
PO Box 877906
Tempe, AZ 85287-7906
ph: 480-965-3246
email: gary.marchant@asu.edu

Check out our blog: [Bits, Bots & Biomarkers | Blawg of the Center for Law, Science & Innovation at ASU's Sandra Day O'Connor College of Law](#)

Henry I. Miller, M.D.
Robert Wesson Fellow in Scientific Philosophy
& Public Policy
Hoover Institution | Stanford University
Stanford, CA 94305-6010
U.S.A.
Phone: +1 (650) 725-0185
Email: henry.miller@stanford.edu